PATENT
Attorney Docket No. 34655-703.831

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:	Confirmation No.: 6542
Inventor: Alan Breen	Examiner: Helene C. Bor
Application No.: 10/520,489	Group Art Unit: 3768
Filed: January 7, 2005	Customer No.: 21971
Title: METHOD FOR IMAGING THE RELATIVE MOTION OF SKELETAL SEGMENTS	

FILED ELECTRONICALLY ON: 10/10/08

DECLARATION OF ALAN BREEN UNDER 37 C.F.R. § 1.132

I, **Alan Breen**, declare as follows:

1. I am the inventor of all of the claims of the patent application identified above originally filed as **PCT/GB2003/002934** on July 8, 2003, claiming priority to **GB 0215848.3** filed July 9, 2002, and to **GB 0226264.0** filed November 11, 2002, and inventor of the subject matter described and claimed therein.

2. I have reviewed the European Journal of Chiropractic article cited, attached as **Exhibit A,** entitled "Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings." The authors of the article are: J. Muggleton, M. Kondracki, J. Wright, A. Morris and myself.

3. I understand that the rules of inventorship differ from those relating to authorship and I believe that I am the sole inventor of the claimed application.

4. The invention of the subject matter claimed in this application, and disclosed in the European Journal of Chiropractic article, was conceived by my and reduced to practice by me, before the submission of the European Journal of Chiropractic article.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001.

Executed on this 30 day of September 2008.

Alan Breen, D.C., Ph.D.

European Journal of Chiropractic, 2002, **50**, 27–32

Original article

Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings

A. C. BREEN DC PhD
Institute for Musculoskeletal Research and Clinical Implementation, Anglo-European College of Chiropractic, Bournemouth, UK

J. MUGGLETON
Institute of Sound and Vibration Research, University of Southampton, Southampton, UK

M. KONDRACKI
Institute for Musculoskeletal Research and Clinical Implementation, Anglo-European College of Chiropractic, Bournemouth, UK

J. WRIGHT & A. MORRIS
Department of Clinical Radiology, Salisbury District General Hospital, Salisbury, UK

Lumbar spine motion palpation compared with objective intervertebral motion analysis: preliminary findings
A. C. Breen, J. Muggleton, M. Kondracki, J. Wright & A. Morris. *European Journal of Chiropractic*, 2002, **50**, 27–32
The present paper describes a comparison between lumbar spine motion palpation findings and the objective assessment of passive intervertebral side-bending using X-ray fluoroscopic sequences. Sixteen male volunteers underwent conventional lumbar motion palpation by an experienced chiropractor prior to fluoroscopic screening in passive side-bending motion. The X-ray sequences were analysed for intervertebral rotational motion using an image processing technique and the results were compared with the palpation findings. Twenty-five lumbar motion segments between L2 and L5 met the reliability criteria for assessment. Palpation suggested that 10 of these were 'free' and 15 'partially fixed'. (No complete fixations were found.) The 'partially fixed' segments were found to have 2.3° less range than the 'free' segments ($P=0.08$). These results are encouraging and provide support for the scientific validity of palpation as a clinical technique for locating vertebral levels and detecting intervertebral range restrictions.

Introduction

The palpation of osseous landmarks is one of the most common examination procedures in European chiropractic (Pedersen 1994). However, its role in clinical decision-making may be out of proportion to its reliability. The 1980s and early 1990s saw a number of serious attempts to evaluate this gap with studies involving calibration against known standards, test–retest reliability, internal consistency, and inter- and intra-observer reliability (Breen 1992). The statistical methodologies needed to underpin these evaluations were also reviewed (Haas 1991), helping to promote an appreciation of the limits of reliability and what reasonable limits could be.

Palpation of the spine has received most of the attention directed at reliability (Russell 1983), addressing *in vivo* observer variations in the cervical (Mior *et al.* 1985), thoracic (Christensen *et al.* 2001) and lumbar spines

Correspondence: Dr A. C. Breen, Institute for Musculoskeletal Research and Clinical Implementation, Anglo-European College of Chiropractic, 13–15 Parkwood Road, Boscombe, Bournemouth, Dorset BH5 2DF, UK (e-mail: imrci.abreen@aecc.ac.uk).

Exhibit A

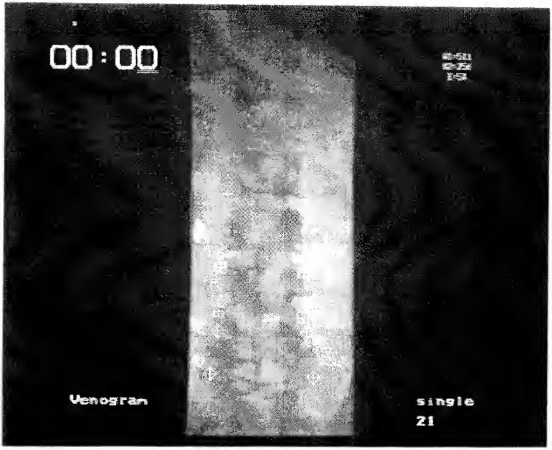

Figure 1. Image from a digital fluoroscopic motion sequence of the lumbar spine. The cursor marks record the coordinates of the instantaneous vertebral position.

(Keating *et al.* 1990; Maher & Adams 1994). Validity against a known standard has proved to be even more difficult, the construction of model environments providing the certainty of a 'gold standard' at the expense of realism (Harvey & Byfield 1991). These investigations seldom distinguished between the amount of intersegmental movement during active or passive spinal motion, the stiffness of the motion segments to pressure (joint challenge), or the patient's reaction to either. In summary, the studies so far have suggested that motion palpation is not a very reliable procedure, especially between observers, and there is little evidence that it detects actual stiffness in spinal motion segments. The evaluation of this requires a comparison between palpation findings and objective segmental motion measurements in living subjects.

However, such a technique has existed since the late 1980s, when the present authors' research group embarked on the development of a device based on the image processing of fluoroscopic spinal motion sequences (Fig. 1). They have developed computational algorithms for the analysis and display of the kinematics between vertebrae, and the system has gone through various stages of refinement aimed at reducing the laboriousness of the process (Breen *et al.* 1989, 1990, 1993). One of the most helpful steps in this has been the automatic tracking of images (Muggleton & Allen 1997), which allows the operator respite from coordinate marking, and along with modern computer storage capacities and processor speeds, now enables many more images in the sequence to be accessed.

The present paper describes a comparison between lumbar spine motion palpation findings and the objective assessment of passive intervertebral side-bending using digitized X-ray fluoroscopic sequences. This was part of a larger study done to inform the development of the system. At the time of the present study, the authors' tracking method was limited to coronal plane (side-bending) motion.

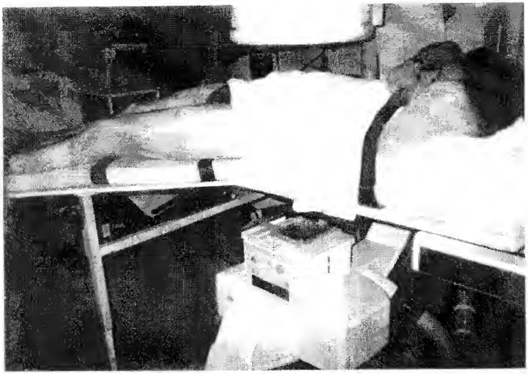

Figure 2. Subject undergoing passive side-bending motion during screening.

Subjects and methods

Subjects

Sixteen male volunteers were included in the present study. None had suffered back pain in the previous year or had manipulation to their lumbar spines in the previous month. Informed consent was obtained and the study carried ethical approval from the Salisbury Local Research Ethics Committee, Salisbury, UK.

Palpation method

Prior to examination, the age, height and weight of the subjects were recorded. Each subject then sat on a flat bench with their feet in contact with the floor and their hands on their thighs. The palpator was an experienced chiropractor who first located the spinous processes from L1 to S1 and marked them with a skin pencil (Burton *et al.* 1990). The palpator's thumb was placed against the lateral aspect of each interspinous junction so that both spinouses could be felt. The subjects were encouraged to relax and allow passive side-bending motion of the trunk. This was initiated and controlled by the palpator's other hand, which side bent the trunk, first left, then right, with a contact across the middle trapezius region. To avoid altering flexibility by virtue of the palpation method itself, no pressure ('joint challenge') was exerted against the spinouses. Each motion segment was recorded as being either free, partially fixed or completely fixed.

Acquisition of images

After palpation, subjects were sedentary until, within 20 min, they underwent passive side-bending in the supine position whilst undergoing fluoroscopic screening of their lumbar spines (Fig. 2). This was carried out in the Special Procedures Room of the X-ray Department at Salisbury District Hospital, Salisbury, UK. A motorized table was fixed to a digital X-ray machine (Polystar, Siemens, Munich, Germany). This equipment incorporates an above table image intensifier and an automatic exposure control. The table's base section could be abducted by 80° (40° left to 40° right). Screening was executed with gonadal shielding after a brief trial of the range of motion without exposure to ensure that the subject was comfortable at the extremes of the range, familiar with the procedure and adequately stabilized. Additional lead rubber shielding was used to reduce the flare produced during screening. The central X-ray beam was centred at the level of L3 and the sequence of motion was from neutral to 40° left to 40° right, then back to neutral. Exposure times, current (mA), voltage (kV) and absorbed radiation were recorded.

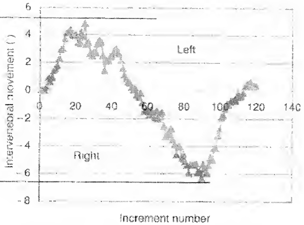

Figure 3. Range of motion measurement: (▲) L4–5.

During screening, a personal computer interfaced with the analogue output of the image intensifier sampled the image sequence. This was coordinated with the motorized table motion and the exposure. Images were digitally sampled at a rate of five frames per second with the simultaneous recording of time code on each frame. Files were stored on compact disc for later analysis.

Processing of image data

All images were subjected to an automated tracking protocol based on the electronic template labelling of each vertebral body (Muggleton & Allen 1997). This procedure generated a vertebral angle for each segment in each frame, and subsequently, the angles between them by subtraction. Intervertebral angles were generated for approximately 120 frames of the motion, which constituted the entire range. The range of intersegmental side-bending was measured for each vertebral motion segment as the greatest angular difference between end-of-range positions (Fig. 3). This procedure was undertaken by a different observer to the palpator.

Reliability of image analysis

Reliability was addressed in two ways. The first was by selecting three subjects thought to represent the spread of tissue types across the sample and tracking their motion sequences 10 times for each of the 120 increments of rotational motion at each lumbar segment. As a result of this, the L1–2 level was rejected as producing unacceptable errors because of out-of-plane images, as was the L5–S1 because of the small motion range at that level. Two standard deviations of the mean differences

Table 1. Characteristics of subjects and X-ray dosage ($n = 14$)

Variable	Mean ($\pm$ SD)	Range Minimum	Range Maximum
Characteristic			
Age (years)	29.9 ± 6.5	19	40
Body mass index*	24.1 ± 2.0	20.9	28.7
X-ray dosage			
Voltage (kV)	73.3 ± 3.7	68	83
Current (mA)	1.2 ± 0.2	0.9	1.8
Time (min)	0.49 ± 0.05	0.4	0.6
Absorbed dose (mSv)	0.17 ± 0.08	0.1	0.3

*Calculated as the subject's weight (kg) divided by the square of her or his height (m).

between tracking sequences were considered to represent the instrument measurement errors (IMEs; Haas 1991) for each motion segment.

The second reliability assessment consisted of analysing each subject twice. The second trace of motion for each vertebra had to overlie the first on visual inspection, especially at the extremes of range. Those that did not were rejected from the analysis. The differences between ranges for all motion segments at each individual level were analysed for significance using the SPSS PC+ Version 10 computer program.

Results

The present study population were relatively young and fit, with a mean age (± SD) of 29.9 ± 6.5 years and a mean body mass index (± SD) of 24.1 ± 2.0 (Garrow 1988) (Table 1). All participants tolerated the examination easily. The mean X-ray dose was equal to approximately two-fifths of the dose of a plain posterior–anterior lumbar film (Wall & Hart 1997). This was mainly attributable to short exposures and low milliamperage.

The instrument measurement errors for the L2–3, L3–4 and L4–5 motion segments were 4.0°, 2.3° and 1.7°, respectively. Twenty-five palpated motion segments from L2–3 to L4–5 in 14 of the subjects met the reliability criteria for analysis. Ten of these had been recorded as 'free' and 15 as 'partially fixed'. None were recorded as completely fixed, possibly reflecting the age and asymptomatic nature of the population.

The mean ranges (± SD) of the 'free' and 'partially fixed' segments from image analysis were 15.1 ± 3.71° and 12.8 ± 3.19°, respectively. This average difference of

Table 2. Palpation against objective intervertebral rotation measurements

Free segments		Partially fixed segments	
Subject	Range (°)	Subject	Range (°)
L2–3			
DE	15.25	RI	12.5
		RG	11.00
Mean (± SD)	15.25	11.75 ± 1.06	
L3–4			
DE	16.5	RG	11.5
RJ	9.75	OT	14
DK	18.5	GD	16.5
BM	18.25	GP	15
JM	11.25		
Mean (± SD)	14.85 ± 4.07	14.25 ± 2.10	
L4–5			
DE	17	MG	10.5
RJ	10	RG	15
JW	14.25	MM	17.75
BM	20.25	OT	14
		WO	10.5
		DK	4.24
		GD	14
		JM	12
		JO	13.5
Mean (± SD)	15.38	12.38 ± 3.80	

2.3° did not quite reach statistical significance ($P=0.08$, two tailed analysis, unpaired t-test assuming unequal variances).

Table 2 shows the subject-by-subject comparison between palpation findings and measured ranges in the subjects. No conclusion can be made about the differences between the 'partially fixed' and 'free' segments at the L2–3 level since the mean difference between them of 3.5° was inside the IME of 4.0° for this level. At L3–4, these differences were small and also within the IME. At L4–5, the mean difference of 3° was greater than the IME of 1.7°, although not statistically significant ($P=0.28$, Mann-Whitney U-test).

Discussion

Reliability of the objective measure

The use of automated image tracking and the possibility of averaging repeated analyses provides a method for minimizing errors, overcoming an important impediment in this work. However, acceptable reliability has been possible using such a system without automated tracking (Humphreys *et al.* 1990). The above authors calculated interobserver IMEs of 2° (four observers) and intra-observer IMEs of 0.65° based on images where the central ray was aligned at the level of interest (L4–5), optimizing reliability. However, there are limits to this. Coyle (1987) demonstrated that, on a conventional X-ray image of a vertebra, it would be difficult to reliably calculate an intervertebral angle under 2° with an attributable coordinate mark. However, image resolution is constantly improving with fluoroscopy, which will reduce this problem.

The statistical power of studies to detect differences is lowered when the effect (in this case, degree of intervertebral stiffness) is low. Therefore, studies using young, asymptomatic subjects are not ideal, since their motion segments can be expected to be relatively flexible. In this regard, the present data can be regarded as a starting point for future work with symptomatic populations. In such studies, skin-marking over the spinouses is recommended.

Active or passive motion?

The development of a non-weight-bearing passive motion apparatus was compatible with the investigation of disco-ligamentous and involuntary muscular effects on intersegmental motion. By contrast, active motion in a weight-bearing position would apply the additional effects of disc and facet compression, and voluntary muscle activity. It would have been more representative of passive motion if the palpation in the present study had been undertaken with the patient on the passive motion table, but less representative of motion palpation techniques.

Conclusion

The present study shows that motion palpation findings may reflect actual *in vivo* intervertebral motion. However, the use of a small number of young, asymptomatic subjects undoubtedly weakened its statistical power. Nevertheless, these results are encouraging, and future work with a larger number of symptomatic subjects involving sagittal plane motion would yield a larger number of segments and a greater selection of kinematic patterns for analysis. This would confirm (or otherwise) the findings reported by the present authors.

Acknowledgements

We gratefully acknowledge the financial support of the European Chiropractors' Union Research Fund for the programme of work of which this was a part. We also thank all the volunteer subjects who gave freely of their time to help us.

References

Breen A. C. (1992) The reliability of palpation and other diagnostic methods. *Journal of Manipulative and Physiological Therapeutics* **15**, 54–56.

Breen A. C., Allen R. & Morris A. (1989) Spine kinematics: a digital videofluoroscopic technique. *Journal of Biomedical Engineering* **11**, 224–228.

Breen A. C., Brydges R., Nunn H., Kause J. & Allen R. (1993) Quantitative analysis of lumbar spine intersegmental motion. *European Journal of Physical Medicine and Rehabilitation* **3**, 182–190.

Breen A. C., Humphreys B. K., Rice S., Cheung P., Osborne A. & Allen R. (1990) The analysis of spine kinematics using digital videofluoroscopy. In: *Proceedings of the 7th Meeting of the European Society of Biomechanics*, Aarhus, 8–11 July 1990.

Burton A. K., Edwards V. A. & Sykes D. A. (1990) Invisible skin marking for testing palpatory reliability. *Manual Medicine* **5**, 1–3.

Christensen H. W., Vach W., Vach K., Manniche C., Haghfelt T. & Hoilund-Carlsen P. F. (2001) Palpation of the upper thoracic spine: an observer variability study. In: *Proceedings of the 6th Biennial Congress of the World Federation of Chiropractic*, Paris, 21–26 May 2001, pp. 331–332. World Federation of Chiropractic, Toronto.

Coyle B. (1987) Accuracy of measurement from points marked on X-rays. In: *2nd Annual Conference on Research and Education*, 1987, pp. 45–47. The Pacific Consortium for Chiropractic Research, Belmont, CA.

Garrow J. S. (1988) *Obesity and Related Diseases*. Churchill Livingstone, Edinburgh.

Haas M. (1991) Statistical methodology for reliability studies. *Journal of Manipulative and Physiological Therapeutics* **14**, 119–132.

Harvey D. & Byfield D. (1991) Preliminary studies with a mechanical model for the evaluation of spinal motion palpation. *Clinical Biomechanics* **6**, 79–82.

Humphreys K., Breen A. & Saxton D. (1990) Incremental lumbar spine motion in the coronal plane: an observer variation study using digital videofluoroscopy. *European Journal of Chiropractic* **38**, 56–62.

Keating J. C., Bergmann T. F., Jacobs G. E., Finer B. A. & Larson K. (1990) Interexaminer reliability of eight evaluative dimensions of lumbar segmental abnormality. *Journal of Manipulative and Physiological Therapeutics* **13**, 463–470.

Maher C. & Adams R. (1994) Reliability of pain and stiffness assessments in clinical manual lumbar spine examination. *Physical Therapy* **74**, 801–811.

Mior S. A., King R. S., McGregor M. & Bernard M. (1985) Intra- and inter-examiner reliability of motion palpation in the cervical spine. *Journal of the Canadian Chiropractic Association* **29**, 195–198.

Muggleton J. M. & Allen R. (1997) Automatic location of vertebrae in digitised videofluoroscopic images of the lumbar spine. *Medical Engineering and Physics* **19**, 77–89.

Pedersen P. (1994) A survey of chiropractic practice in Europe. *European Journal of Chiropractic* **42** (Suppl.), 3–28.

Russell R. (1983) Diagnostic palpation of the spine: a review of procedures and assessment of their reliability. *Journal of Manipulative and Physiological Therapeutics* **6**, 181–183.

Wall B. F. & Hart D. (1997) Revised radiation doses for typical X-ray examinations. *British Journal of Radiology* **70**, 437–439.